APPEAL BRIEF
EXAMINING GROUP 1614
Patent Application
Docket No. ALL-T101D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Leslie A. Royds
Art Unit	:	1614
Applicant	:	Ann de Wees Allen
Serial No.	:	10/643,298
Filed	:	August 18, 2003
Conf. No.	:	4203
For	:	Composition Comprising L-Arginine as a Muscle Growth Stimulant and Use Thereof

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APPEAL BRIEF

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February 8, 2008

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APPENDICES

I. REAL PARTY IN INTEREST

The real party in interest is Ann de Wees Allen.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

Pending claims 1-3, 6-9, and 12-15 were finally rejected in the Office Action of June 20, 2007 under 35 U.S.C. §112, second paragraph and under 35 U.S.C. §103(a). Claims 1, 6, and 7 were also finally rejected in the Office Action of June 20, 2007 under 35 U.S.C. §102(b). Claims 4 and 10 were cancelled by Amendment dated January 30, 2006. Claims 5 and 11 were cancelled by Amendment dated April 4, 2007. The rejections of claims 1-3, 6-9, and 12-15 are appealed herein.

IV. STATUS OF AMENDMENTS

There have been no amendments after the final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The independent claims involved in this appeal are claims 1, 6, and 12. Claim 1 is directed to a composition for stimulating muscle growth comprising any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate, and vitamin B5 (page 3, lines 26-33; page 9, lines 7-15; page 10, line 11 through page 11, line 21; page 15, lines 15-23) wherein the composition further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine (page 3, lines 16-19; page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17). The composition does not contain any amino acids except the amino acids in the amino acid component (page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17).

Claim 6 is directed to a method for stimulating growth of muscle in a mammal (page 2, lines 30-33; page 4, lines 5-13). The method comprises administering to a mammal a muscle growth stimulating amount of a composition comprising any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate, and vitamin B (page 3,

lines 26-33; page 4, lines 5-13; page 9, lines 7-15; page 10, line 11 through page 11, line 21; page 15, lines 15-23) wherein the composition further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine (page 3, lines 16-19; page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17). The composition does not contain any amino acids except the amino acids in the amino acid component (page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17).

Claim 12 is directed to a method for stimulating an immune response in a mammalian organism (page 4, lines 14-24). The method comprises administering to a mammal in need of an immune response an effective amount of a composition comprising any one or combination of ingredients selected from the group consisting of chromium, choline, sodium borate, and vitamin B (page 3, lines 26-33; page 4, lines 14-24; page 9, lines 7-15; page 10, line 11 through page 11, line 21; page 15, lines 15-23) wherein the composition further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine (page 3, lines 16-19; page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17). The composition does not contain any amino acids except the amino acids in the amino acid component (page 3, lines 26-33; page 9, lines 3-8; page 10, lines 3-10; page 15, lines 10-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-3, 6-9, and 12-15 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 6, and 7 have been rejected under 35 U.S.C. §102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287, hereinafter "Winitz"). Claims 1-3 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Winitz in view of Durst (U.S. Patent No. 3,434,843, hereinafter "Durst") and Millman (U.S. Patent No. 4,871,550, hereinafter "Millman"). Claims 6-9 and 12-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990, hereinafter "Rudman"), Dudrick *et al.* (U.S. Patent No. 5,026,721, hereinafter referred to as "Dudrick"), and Boynton *et al.* (U.S. Patent No. 5,087,624, hereinafter referred to as "Boynton").

VII. ARGUMENT

A. Claims 1-3, 6-9, and 12-15 meet the requirements of 35 U.S.C. §112, second paragraph because they particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1-2, 6-8, and 12-15

Claims 1-2, 6-8, and 12-15 were finally rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Appealed claims 1-2, 6-8, and 12-15 stand or fall together for purposes of the Appeal of this rejection under 35 U.S.C. §112, second paragraph.

The Examiner asserts on pages 2-4 of the June 20, 2007 Office Action that independent claims 1, 6, and 12 use "conflicting" transitional language (while the Office Action actually cites claims 1, 6, and 11, this appears to be a typographical error since claim 11 was cancelled in the Amendment dated April 4, 2007).

It appears that this rejection is entirely premised on the Examiner's erroneous assumption that the presence, in a single claim, of the words "consisting of" and "comprising" per se causes the claim to be indefinite. This assumption is contrary to established case law and, in this case, it is apparent that there is no ambiguity with regard to the scope of the claims.

The composition referred to in each of the claims at issue comprises any one or a combination of ingredients selected from the group consisting of chromium, choline, sodium borate, and vitamin B5. The term "comprises" indicates that the composition can include components in addition to those that are recited (see MPEP §2111.03). The phrase "consisting of chromium, choline, sodium borate, and vitamin B5" indicates that the group includes only these components. Thus, the composition must have one of those ingredients. Additionally, the composition "further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine." This phrase indicates that the composition must include an amino acid component. The use of "consists of" specifies that the amino acid component includes only these components.

Section 2111.03 of the MPEP states that, "when the phrase 'consists of' appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause." Thus, the use in independent claims 1, 6, and 12 of the phrases "comprises" and "consists of" does not render the claims indefinite. In each claim, it is clear which elements are intended to be limited by the phrase "consists of."

Moreover, the claims do not read upon a composition that includes amino acids other than those recited in the claim.

In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. §112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent (*Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283, Fed. Cir. 2000; *In re Larsen*, No. 01-1092, Fed. Cir. May 9, 2001; see also MPEP §2173.02).

Each independent claim (claims 1, 6, and 12) ends with the clause, "wherein said composition does not contain any amino acids except the amino acids in the amino acid component." When considering the claim as a whole, it is clear to a skilled artisan that no amino acids can be present in the composition except those explicitly enumerated in the amino acid component. Thus, even though the constitution of the composition is described with the transitional phrase "comprises," a skilled artisan, having read the entirety of claim 1, would come to the unambiguous conclusion that the composition cannot include any amino acids not recited as part of the amino acid component.

As discussed above, claims 1-2, 6-8, and 12-15 particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Respectfully, the Appellant requests reversal of the Examiner's rejections of claims 1-2, 6-8, and 12-15 under 35 U.S.C. §112, second paragraph.

Claims 3 and 9

Claims 3 and 9 were also finally rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Appealed claims 3 and 9 stand or fall together for purposes of the Appeal of this rejection under 35 U.S.C. §112, second paragraph.

In the Office Action dated June 20, 2007, the Examiner applied the same reasoning to claims 3 and 9 as discussed above in the "Claims 1-2, 6-8, and 12-15" subsection. Thus, the arguments presented in the previous subsection are incorporated herein in their entirety. However, the Examiner also rejected claims 3 and 9 for failing to narrow the subject matter of the independent claim from which they depend.

The Examiner asserts at page 4 of the June 20, 2007 Office Action that claims 3 and 9 broaden the composition of the independent claim because each claim describes dosage ranges of each of the components. The Appellant respectfully disagrees with this assertion because claims 3 and 9 each clearly limit the scope of the independent claim from which it depends. The composition referred to in independent claims 1 and 6 does not have any amounts listed for each component per dosage. Thus, each component can be present in the composition in any amount. Claims 3 and 9, on the other hand, list ranges for several of the components of the composition of claims 1 and 6, thereby narrowing the scope of the claimed subject matter from a composition having the listed components present in any amount to one wherein several of the components are present in a given range of amounts.

The Appellant submits that, by limiting the amount of several of the components present in the composition, claims 3 and 9 narrow the scope of the independent claims from which they depend.

Respectfully, the Appellant requests reversal of the Examiner's rejections of claims 3 and 9 under 35 U.S.C. §112, second paragraph.

B. Claims 1, 6, and 7 are patentable because Winitz does not disclose the claimed invention.

Claims 1, 6, and 7 were finally rejected under 35 U.S.C. §102(b) as being anticipated by Winitz. Appealed claims 1, 6, and 7 stand or fall together for purposes of the Appeal of this rejection under 35 U.S.C. §102(b).

The Appellant notes that this rejection appears to result largely, if not entirely, from the Examiner's misinterpretation of the claims as discussed above. Specifically, the Examiner

applies Winitz to the claimed invention under the interpretation that the present invention can include amino acids in addition to those recited in the claims. As discussed in Section A above, the claimed invention cannot include any amino acids that are not part of the amino acid component. While the Appellant believes the correctly interpreted claims are plainly not anticipated by Winitz, additional remarks are presented for further clarity.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983) (emphasis added). 221 USPQ at 485.

The compositions taught in Winitz each contain a plethora of amino acids, many more than the four recited as the amino acid component in claim 1 of the present invention (see Winitz, Tables 1-2 and Examples I-VI). The claims of the present invention require that the only amino acids present in the composition are those of the amino acid component: L-arginine, L-leucine, L-isoleucine, and L-valine. By contrast, the Winitz reference discloses compositions with many additional amino acids. The inclusion of these additional amino acids is explicitly prohibited by the claims of the present invention. There is no mention whatsoever in Winitz of a composition in which the only amino acids present are those of the amino acid component of the present invention. Thus, Winitz does not disclose within its four corners all of the elements of the claimed invention.

Respectfully, the Appellant requests reversal of the Examiner's rejections of claims 1, 6, and 7 under 35 U.S.C. §102(b).

C. Claims 1-3 are patentable because the combination of Winitz, Durst, and Millman does not render the subject invention obvious.

Claims 1-3 were finally rejected under 35 U.S.C. §103(a) as being unpatentable over Winitz in view of Durst and Millman. Appealed claims 1-3 stand or fall together for purposes of the Appeal of this rejection under 35 U.S.C. §103(a).

Once again, the Appellant notes that this rejection appears to be based largely, if not entirely, on the Examiner's incorrect interpretation of the claimed invention as allowing additional amino acids besides those that are part of the recited amino acid component. As discussed in Section A above, the claimed invention cannot include any amino acids that are not part of the recited amino acid component. While the Appellant believes the correctly interpreted claims are plainly not obvious over the cited combination of references, additional remarks are presented for further clarity.

As discussed in Section B above, Winitz teaches only compositions which contain a multitude of amino acids. Additionally, Durst and Millman each disclose only compositions which include many amino acids besides those recited in the amino acid component of claim 1 (see Durst, Example 1; see Millman, Table 1, and Examples 1-4). Thus, there is no disclosure in any of the cited references of a composition in which the only amino acids present are those of the amino acid component of claim 1 of the present invention. While the applicant recognizes that the combination of cited references must be viewed as a whole, a skilled artisan could not have arrived at the subject invention based on these references because the combination contains no mention whatsoever of a composition with only the four amino acids of the amino acid component of claim 1.

Accordingly, the Appellant respectfully requests reversal of the Examiner's rejections of claims 1-3 under 35 U.S.C. §103(a).

D. Claims 6-9 and 12-15 are patentable because the combination of Rudman, Dudrick, and Boynton does not render the subject invention obvious.

Claims 6-9 and 12-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman, Dudrick, and Boynton. Initially, it is noted that the Rudman reference was

actually authored by Pearson and Shaw with an opening quote attributed to Rudman, but the Appellant will refer to it as the Rudman reference as the Examiner has. Appealed claims 6-9 and 12-15 stand or fall together for purposes of the Appeal of this rejection under 35 U.S.C. §103(a).

Again, the Appellant notes that this rejection appears to be based on the Examiner's incorrect interpretation of the claimed invention as allowing additional amino acids besides those that are part of the amino acid component. As discussed in Section A above, the claimed invention cannot include any amino acids that are not part of the recited amino acid component. While the Appellant believes the correctly interpreted claims are plainly not obvious over the cited combination of references, additional remarks are presented for further clarity.

The current inventor has found that a composition with only four specific amino acids is highly effective in promoting muscle growth. This particular formulation is quite unexpected because, for example, it does not include lysine and, at the time of the invention, those skilled in the art believed that arginine should be combined with lysine.

Specifically, a noted disadvantage associated with L-arginine is that when administered on its own, arginine tends to promote herpes 1 and 2, which gives rise, amongst other adverse effects, to mouth sores and genital discomfort. It is known that L-lysine inhibits the growth of such viruses, and so lysine is conventionally administered with arginine to minimize the onset of herpes. The claims of the present invention exclude the presence of any amino acid, including lysine, not recited as part of the amino acid component.

The Supreme Court has stated that "when the (purported) prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S.Ct. 1727 (2007). Here, the claimed invention combines arginine with three other amino acids and without lysine. The state of the art and the cited combination of references (see Dudrick, column 2, lines 48-50) taught that lysine should be used with arginine, thus teaching away from the present invention. Furthermore, a skilled artisan at the time of the current invention would not have found it obvious to create a composition with arginine that did not include lysine. Due to the severity of herpes viruses, a person skilled in the art would have made sure to take precautions that were thought to be necessary to prevent the viruses, including using lysine together with arginine.

Additionally, there is no disclosure in any of the cited references of a composition containing the four amino acids of the amino acid component of claim 1 with no other amino acids. For example, the Rudman reference contains no disclosure of L-leucine, L-isoleucine, or L-valine, and Boynton does not even discuss any amino acids. While Dudrick discloses an array of amino acids, the reference specifically teaches that its supplement necessarily includes, as "primary" amino acids, glutamic acid, arginine, leucine, valine, and lysine (column 3, lines 34-39). Thus, Dudrick teaches away from the current invention by incorporating two amino acids specifically excluded from the claimed invention.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, *supra*. Here, there is no reason for a skilled artisan to combine the cited references to arrive at the claimed invention, which contains L-arginine, L-leucine, L-isoleucine, L-valine, and no other amino acids. The only cited reference that even discloses leucine, isoleucine, or valine, the Dudrick reference, specifically teaches that its supplements should also "necessarily" include glutamic acid and lysine (column 3, lines 34-39).

Since there is absolutely no disclosure whatsoever in the cited references of a composition containing L-arginine, L-leucine, L-isoleucine, L-valine, and no other amino acids, the applicant respectfully submits that, without the benefit of the applicant's own disclosure, a skilled artisan could not have arrived at the claimed invention. Instead, the Examiner has used hindsight reconstruction. The applicant's own disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C. §103, as was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969).

As discussed above, a skilled artisan could not have arrived at the claimed invention based on the combination of cited references. Accordingly, the Appellant respectfully requests reversal of the Examiner's rejections of claims 6-9 and 12-15 under 35 U.S.C. §103(a).

E. Conclusion

In view of the foregoing, the Appellant urges the Board to overrule the outstanding rejections under 35 U.S.C. §§112 (second paragraph), 102(b), and 103(a) and pass this application to issuance.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A composition for stimulating muscle growth, wherein said composition comprises any one or combination of ingredients selected from the group consisting of chromium; choline; sodium borate; and vitamin B5; and wherein said composition further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine; and wherein said composition does not contain any amino acids except the amino acids in the amino acid component.

2. The composition, according to claim 1, wherein said L-arginine is present in an amount of 1.0 g to 60.0 g per serving.

3. The composition, according to claim 1, wherein said composition comprises per dosage:

L-Arginine	1.0-60.0 g
L-Leucine	25-200 mg
L-Isoleucine	25-200 mg
L-Valine	25-200 mg
Chromium	10-50 mcg
Choline	10.0-700 mg.

Claim 4 was cancelled by Amendment dated January 30, 2006.

Claim 5 was cancelled by Amendment dated April 4, 2007.

6. A method for stimulating growth of muscle in a mammal, said method comprising administering to a mammal a muscle growth stimulating amount of a composition comprising any one or combination of ingredients selected from the group consisting of chromium; choline; sodium borate; and vitamin B5; and wherein said composition further comprises an amino acid component that consists of L-arginine, L-leucine, L-isoleucine, and L-valine; and wherein said composition does not contain any amino acids except the amino acids in the amino acid component.

7. The method, according to claim 6, wherein said composition is orally administered.

8. The method, according to claim 6, wherein said L-arginine is present in an amount of from 1.0 to 60.0 g per serving.

9. The method, according to claim 6, wherein the composition comprises per dosage:

L-Arginine	1.0-60.0 g
L-Leucine	25-200 mg
L-Isoleucine	25-200 mg
L-Valine	25-200 mg
Chromium	10-50 mcg
Choline	10.0-700 mg.

Claim 10 was cancelled by Amendment dated January 30, 2006.

Claim 11 was cancelled by Amendment dated April 4, 2007.

12. A method for stimulating an immune response in a mammalian organism, said method comprising administering to a mammal in need thereof an effective amount of a composition comprising any one or combination of ingredients selected from the group consisting of chromium; choline; sodium borate; and vitamin B5; and wherein said composition further comprises an amino acid component that consists of L-arginine, L-leucine, L-isoleucine, and L-valine; and wherein said composition does not contain any amino acids except the amino acids in the amino acid component.

13. The method according to claim 12, wherein said L-arginine is administered intravenously as an aqueous solution in an amount of 1-10 grams per day.

14. The method according to claim 12, wherein said L-arginine is administered in association with an immune system stimulator.

15. The method according to claim 14, wherein said immune system stimulator is vitamin C and is administered in an amount of 1-10 grams per day.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.